REMARKS

I. Status of the Application

This paper responds to a non-final Office Action, which was mailed on April 10, 2003. The original application was filed with claims 1-17. In a response to a telephonic restriction requirement, Applicant elected to pursue Group I invention (claims 1-9) and gabapentin species. A non-final Office action mailed on September 13, 2001 rejected claims 1-9 and withdrew from consideration claims 10-17 as being drawn to a non-elected invention. Applicant filed a response to the non-final Office action on February 12, 2002, amending claims 1-9 and adding new claims 18-22. A subsequent final Office action mailed on May 30, 2002, rejected claims 1-9 and 18-22. Applicant filed an after-final amendment on July 30, 2002, which was not entered. Applicant subsequently filed a Request for Continued Examination (RCE), which amended claim 1 and added new clams 23 and 24. The present paper amends claims 1, 9, 18, 20, and 24, and cancels claims 10-17 without prejudice or disclaimer. Accordingly, claims 1-9 and 18-24 are currently under consideration. Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks.

By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Amendment of Claims 1, 9, 18, 20, and 24

Applicant has rewritten claim 24 in independent form, and has amended all of the independent claims (1, 18, and 24) so that they each require "an auxiliary agent for manufacturing a pharmaceutical preparation" (pages 2, 12, and 13 of this amendment). Applicant has amended claim 1 so that it no longer reads on pharmaceutical preparations in which the 4-amino-3-substituted-butanoic acid derivative is given by R2 being a "phenyl or naphthyl group which is mono-, di- or tri-substituted with a halogen atom" (page 5 of this amendment). Applicant has also eliminated the provisos in claim 1 regarding glycine and methyl-D-aspartic acid (page 9 of this amendment). Additionally, Applicant has amended claim

24 so that it recites the α amino acids listed in original claim 3, with the exception of glycine (pages 20 and 21 of this amendment). Finally, Applicant has amended claims 9 and 20 to ensure consistency with amended claim 1 and to correct grammatical informalities (page 12 of this amendment). Applicant submits that none of the amendments introduce new matter.

III. Rejection of Claims 1-9 and 23-24 Under 35 U.S.C. § 112

The present Office action rejected claims 1-9 and 23-24 under 35 U.S.C. § 112, first paragraph, because the specification allegedly failed to provide support for negative limitations or provisos concerning glycine and methyl-D-aspartic acid. As noted above in section II of this paper, Applicant has deleted these provisos from claim 1, and therefore respectfully requests withdrawal of this rejection.

IV. Rejection of Claims 18 and 20 Under 35 U.S.C. § 102

The present Office action rejected claims 18 and 20 under 35 U.S.C. § 102(b) as allegedly being anticipated by Woodruff (US 5,084,479) because it "discloses a solution comprising N-methyl-D-aspartic acid and gabapentin (column 8, line 5)." As noted above in section II of this paper, Applicant has amended independent claims 1, 18, and 24 so that the claimed pharmaceutical preparation includes "an auxiliary agent for manufacturing a pharmaceutical preparation." Since Woodruff does not disclose a pharmaceutical preparation that includes N-methyl-D-aspartic acid, gabapentin, and an auxiliary agent, it cannot anticipate claims 1, 18 and 24. Applicant respectfully requests withdrawal of this rejection.

Furthermore, Woodruff cannot be used to render claims 1, 18, and 24 obvious because it teaches away from any pharmaceutical preparation that includes N-methyl-D-aspartic acid (NMDA), gabapentin, and an auxiliary agent. In Woodruff, solutions of gabapentin and NMDA were apparently used to show that gabapentin reduces depolarization of paraventricular thalamus neurons due to NMDA (column 8, lines 20-49). As described in Woodruff, "these results indicate that gabapentin has additional therapeutic indications . . . [since] over stimulation of NMDA receptors has been implicated in the etiology of neuronal damage induced by anoxia, stroke, hypoglycemia, Huntington's disease, as well as epilepsy" (column 3, lines 9-14). Since Woodruff teaches that gabapentin counteracts the effects of NMDA, and over stimulation of

NMDA receptors has been implicated in neuronal damage, adding NMDA to a pharmaceutical preparation containing gabapentin would run counter to Woodruff's teachings. Applicant therefore submits that all of the claims of the present application are patentable over Woodruff.

V. Rejection of Claims 18 and 20 Under 35 U.S.C. § 103

The present Office action rejected claims 1-9, 19, and 21-24 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Seilor et al. (Gen. Pharmac. Vol. 15, No. 4, pp 367-69, 1984) in view of Costa et al. (US 5,248,678). Applicant respectfully submits that Costa et al. cannot be combined with Seilor et al. because the latter reference teaches away from the combination. According to the Office action, "Seilor et al. teaches or suggests the synergistic anticonvulsant effects of a GABA agonist and alpha-amino acid such as glycine. The reference discloses muscimol as the specific example of a GABA agonist." Seilor et al, however, warns against administering muscimol and glycine together so as "to avoid the potential inhibition of muscimol absorption by glycine" (page 367, Methods section). Thus, not only does Seilor et al. fail to teach or suggest combining gabapentin and an α amino acid, it teaches away from making a pharmaceutical preparation comprised of gabapentin and an α amino acid. Applicant therefore submits that it is improper to combine Seilor et al. and Costa et al., and respectfully requests withdrawal of the rejection.

VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any fees required to file the present amendment have been identified in a fee transmittal that accompanies this paper. However, if any fees required in connection with the filing of this paper have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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